

### **REMARKS**

Applicants note the objection, under 37 C.F.R. §1.83 (a), of the drawings. The Official Action points out that Page 8 of the specification includes a Brief Description of the Drawings section without the inclusion of those drawings.

Applicants have overcome this objection by deleting that portion of the specification, at Page 8, lines 8 to 13, wherein the Brief Description of the Drawing section is set forth. The elimination of this portion of the specification makes moot the objection of record. That is, this deletion not only eliminates the basis for the objection but, furthermore, emphasizes its noncriticality. The claims of the present application are fully supported by the specification of record.

The title of the application has been objected to as being non-descriptive. Applicants have amended the title of the present application to “A Method of Treatment of subjects Suffering Imbalanced Colon Fermentation.” This title emulates the subject matter of the claims. As such, it well defines the invention of the present application.

The specification has been further objected to due to the absence of capital letters to indicate that Raftiline is representative of a trademark. In addition, the Official Action indicates that the term should be accompanied by generic terminology.

Applicants respectfully submit that the requirements of proper trademark usage has been utilized in the specification of the present application. As indicated in the Official Action, the use of a trademark is permissible in patent applications. That the proprietary nature of a trademark marks should be respected and every effort made to prevent its use in any matter which may adversely affect its validity has also been observed.

Attention is directed to the use of that of the term Raftiline<sup>R</sup>, at Page 20, line 8 of the specification. The term is used after the recitation of the generic product for which the trademark

is used, inulin. Not only is the identity of the generic product provided but, in addition, the manufacturer of the inulin under the trademark Raftiline<sup>R</sup>, Orafti, is also set forth.

Not only is the generic product identified but so too is the clear nature of Raftiline<sup>R</sup> as a trademark, as indicated by the <sup>R</sup> and by the manufacturer Orafti. As such, applicants submit that, rather than diminishing that mark, the present application credits the manufacturer of the inulin and correctly emphasizes that the inulin employed in Example 2 was supplied under the trademark Raftiline<sup>R</sup>. Reconsideration and removal of this ground of rejection is therefore deemed appropriate. Such action is respectfully urged.

Turning to the claims, Claims 7, 17-25 and 31-33 are objected to, under 37 C.F.R. § 1.75(c), as being in improper form insofar as these claims are multiple dependent from another multiple dependent claim.

Applicants have amended their claims and, as amended, no claim in the present application is multiple dependent. As such, it is apparent that no claim in the present application is subject to objection based on its dependency from another multiple dependent claim.

The claims of the present application have been rejected on formal and substantive grounds. Applicants have amended their claims and respectfully submit that all the claims currently in this application are patentable over the rejection of record.

The first formal ground of rejection is directed to Claims 1-6, 8-16 and 26-30. Claims 1-6, 8-16 and 26-30 stand rejected, under 35 U.S.C. § 112 first paragraph, as being non-enabled.

Specifically, the Official Action avers that the specification does not provide enablement for treating and preventing imbalanced colon fermentation or managing lactose intolerance, food allergy, inflammatory bowel disease or celiac disease using any carbohydrate.

It is unnecessary to consider the arguments raised in the Official Action in support of this proposition. Suffice it to say, applicants have amended their claims to limit the carbohydrates within the contemplation of the present invention to polydextrose. This amendment, to all the claims of the present application, overcomes this ground of rejection. Clearly, the utilization of polydextrose in the claimed method of treating a subject suffering from imbalanced colon

fermentation is fully supported by the specification of the present application. Thus, the claimed method of the present application is fully enabled by the specification of the present application. Thus, all the claims of the present application are patentable under 35 U.S.C. § 112, first paragraph.

The second formal ground of rejection is directed to Claims 8 to 11 and 13. Claims 8 to 11 and 13 stand rejected, under 35 U.S.C. § 112, second paragraph, as being indefinite.

Specifically, Claim 8 recites “increasing the tolerance of probiotic lactic acid bacteria.” That phrase, the Official Action argues, is indefinite. Applicants have amended Claim 8 so that Claim 8, as amended, emphasizes that polydextrose is administered in an amount which is effective in increasing the tolerance to probiotic lactic acid bacteria. Furthermore, it adds the rationale for this increased tolerance, e.g. by preventing accumulation of lactic acid in the colon.

The Official Action further states that Claims 9 to 11 recite the limitation “facilitating the management of” to lactose intolerance, food allergy and celiac disease, respectively. The Official Action argues that these claims are indefinite since the term “management” is undefined.

Claims 9 to 11 have each been amended to replace the phrase “facilitating the management of” with “reducing”. This amendment thus recites a method wherein the amount of polydextrose administered is an amount necessary to reduce these adverse conditions. Indeed, the Official Action correctly suggests that this was the term intended when the word “management” was used.

The rejection of Claim 13 is predicated upon the recitation of the limitation “balancing or normalizing the microbial community throughout the colon.” This term is deemed indefinite.

Claim 13 has been amended to add the phrase “by preventing accumulation of lactic acid in the colon”. This phrase clarifies the objected to phrase which has itself been amended to delete “balancing or” therefrom. As amended, Claim 13 now emphasizes that normalizing the microbial community throughout the colon is accomplished by administration of polydextrose, which prevents accumulation of lactic acid in the colon.

The final indefiniteness ground of rejection is directed to Claim 30. Claim 30 stands rejected as being indefinite for its absence of antecedent basis. Specifically, there is no antecedent basis for the recitation of polydextrose.

The amendment of Claim 1, wherein the term “carbohydrates” is replaced with - - polydextrose - - , makes moot this ground of rejection. Amended Claim 30 is dependent from Claim 14, which depends from Claim 1. As such, antecedent basis is provided.

It should be further appreciated that Claim 30 has been amended to change its dependency from Claim 15 to Claim 14. That amendment was necessary in view of the cancellation of Claim 15. Moreover, the phrase “preferably from 1:5 to about 5:1” has been deleted. That phrase is indefinite. That limitation has been made the subject of new Claim 34.

A plurality of minor amendments have been made to the claims to correct minor grammatical errors and to provide proper Markush group claim language. These changes are purely ministerial and do not create any file wrapper estoppel.

A plurality of substantive ground of rejection have been imposed in the outstanding Official Action. The first of these is directed to Claim 1-6, 8, 12 and 13. Claim 1-6, 8, 12 and 13 stand rejected, under 35 U.S.C. §102 (b), as being anticipated by Jie et al, Am .J. Clin. Nutr., 72, 1503-1509 (2000).

The amended language of Claim 1, from which all the remaining claims ultimately depend, requires that the method include the step of administering, to a subject suffering lactic acid accumulation, a food or feed product containing polydextrose. That alone predicates novelty over Jie et al. The Jie et al. teaching is limited to the administration of polydextrose as a powder dissolved in warm water (Page 1504, left column, lines 6-8 (below the table)). Thus, the requirement that all the claims of the present application that polydextrose be provided in a food or feed product distinguishes the claims of the present application from the teaching of Jie et al.

It is emphasized, however, that even if reliance on Jie et al. was based on it making obvious the claims of the present application, such a rejection would be similarly deficient. This

is so insofar as the broadest claim of the present application emphasizes that the treatment of the method of Claim 1 is effective in preventing the accumulation of lactic acid throughout the colon of the treaded subject.

As discussed in the specification of the present application, at Page 3, lines 9-16, Jie et al. emphasizes improved bowel function, including the absence of abdominal distention, abdominal cramps, diarrhea or hypoglycemia. Improved bowel function may be prevented or cured by any number of different substances. There is no disclosure in Jie et al. that improved bowel function is based on a lack of lactic acid accumulation in the colon.

It is furthermore noted that Jie et al. concludes that polydextrose ingestion has a significant dietary fiber-like effect with no laxative problems. However, the Jie et al. study does not disclose any information regarding how the polydextrose is fermented in the intestine. The amount of polydextrose, which Jie et al. states is degraded in the intestines, could well have been degraded in the upper parts of the colon, leaving the lower parts without energy.

There are many dietary fibers which have been reported as having the same beneficial effects as those mentioned in Jie et al. for polydextrose. Inulin and oligofructose, two such dietary fibers, are demonstrated in Example 1 of the present application to be quickly fermented without sustained release of energy and with a consequent risk of causing lactic acid accumulation in the colon.

This emphasizes a clear failing in the Jie et al. disclosure. Jie et al. neither describes nor suggests the use of polydextrose to subjects suffering from lactic acid accumulation and diseases caused by such excess lactic acid. According to Jie et al., at Page 1507, left column, lines 2-3, lactic acid can reduce intestinal pH. Since lactic acid is stated to be produced by *Lactobacillus*, and Jie et al. reports that concentrations of *Lactobacillus* were significantly higher in stools after polydextrose intake, the teaching of Jie et al. is to the effect that polydextrose increases lactic acid concentration. This is because pH was reduced in the Jie et al. study and therefore that acidity increase was caused by increased polydextrose intake by the subjects.

On the other hand, the showing presented in the present application surprisingly demonstrates that polydextrose reduces intestinal pH without the accumulation of lactic acid, which would have been expected according to the Jie et al. teaching. The specification of the present application demonstrates that polydextrose reduces pH without accumulation of excess lactic acid not only at the termination of the colon, e.g. in stools, as was the case in Jie et al., but throughout the colon, unlike the Jie et al. teaching.

The invention of the present application, as defined by the amended claims of the present application, is that polydextrose provides sustained release of energy throughout the colon while the opposite is true for numerous other beneficial dietary fibers presently on the market. This surprising effect of polydextrose administration in preventing lactic acid accumulation caused by imbalanced fermentation is not taught by Jie et al.

In summary, the claims of the present application are not only novel over Jie et al. but, in addition, are unobvious over that teaching. This is so insofar as Claim 1 requires that the amount of polydextrose administered to a patient is an amount effective in preventing accumulation of lactic acid. Not only does Jie et al. not make this disclosure but, as indicated by the above remarks, teaches away from this requirement.

The second substantive ground of rejection is directed to Claim 14-16, 26-28 and 30. These claims stand rejected, under 35 U.S.C. §102 (b), as been anticipated by International Publication No. WO 00/40101 to Olinger et al.

The Official Action alleges that Olinger et al. teaches a dietetic chocolate composition sweetened by a composition which includes the polyols maltitol and lactitol in combination with polydextrose. Its composition, the Official Action states, exhibits a surprising high degree of sweetness evidencing a synergistic relationship. From this synergistic result, in terms of sweetness, the Official Action argues that the claims subject to this ground of rejection, wherein the polydextrose is administered in combination with at least one polyol, anticipates Claims 14-16, 26-28 and 30.

It is emphasized that the claims of the present application are directed to a method of preventing unbalanced colon fermentation resulting from lactic acid accumulation. The claims are not directed to any specific food composition. There is no teaching in Olinger et al. of the method of Claims 14, 16, 26-28 and 30. All of these claims require the introduction of an amount of a food or feed product containing polydextrose in an amount effective in preventing the accumulation of lactic acid.

There is, furthermore, in no disclosure in Olinger et al. of administering the composition of that disclosure to a subject suffering from lactic acid accumulation due to imbalanced colon fermentation. As stated earlier, the claims of the present application are not directed to a composition but rather to a method of treating the aforementioned condition.

The third substantive of ground of rejection is directed to the rejection of Claim 29, under 35 U.S.C §102 (b), as being anticipated by Hoebler et al., J. Sci.Food Agric., 80, 1357-1364 (2000).

This ground of rejection has been made moot by cancellation of Claim 29.

The fourth substantive of ground of rejection is directed to Claims 1-6, 8, 12-16, 26-28 and 30. These claims stand rejected, under 35 U.S.C. §102(e) and §102(a), as being anticipated by U.S. Patent Application Publication No. US2003/0157146 A1 to Rautonen et al.

The rejection under 35 U.S.C. §102(a) is presumably predicated upon the publication of the Rautonen et al. patent application on January 14, 2203, prior to the August 16, 2003 filing date of the present application.

Applicants submit herewith a certified copy of the priority document, Finnish Patent Application 20021660, filed September 17, 2002. This application, although a Finnish application, is filed in English and thus no certified translation is necessary. That certified copy of Finnish Patent Application 20021660 perfects priority of the present application so that the effective filing date of the present application is September 17, 2002. That date is earlier than the publication date applied of the Rautonen et al. published patent application.

The September 17, 2002 effective filing date of the present application also eliminates the rejection under 35 U.S.C. § 102(e). That statute requires that an applied US patent be filed by another before the invention of the subject application. That the effective filing date of the present application is earlier than the January 14, 2003 filing date of the applied Rautonen et al. application establishes patentability under 35 U.S.C. §102(e).

The fifth and final substantive of ground of rejection is a provisional rejection made under the judicially created doctrine of obviousness-type double patenting over Claims 1-6, 8,12-16, 26-28 and 30 of the Rautonen et al. application

Applicants submit here with a provisional Terminal Disclaimer which suffices to overcome this ground of rejection.

The above remarks establish that all the substantive grounds of rejection have been overcome. Reconsideration and removal of these grounds of rejection is thus deemed appropriate. Such action is respectfully urged.

The above amendment, enclosed Terminal Disclaimer and remarks establish the patentable nature of all the claims currently in this application. Notice of Allowance and passage to issue of these claims, Claims 1, 5-14, 16-28 and 30-34, is therefore respectfully solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Marvin Bressler", with a long horizontal flourish extending to the right.

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